510(K) Summary K131776

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

JUL 18 2013

2. SUBMITTER NAME AND ADDRESS

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3. 510(k) NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFICATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

510k Number: k131776

Device Proprietary Name: Adolase Control Level 2 and Adolase Control Level 3

Common Name: Aldolase Controls

Purpose for Submission: New Device

Regulatory Classification: Single Specified Analyte Controls, (assayed and unassayed); Class I, reserved

Panel: Clinical Chemistry

Product Code: JJX

21 CFR Number: 21 CFR 862.1660

4. PREDICATE DEVICE PROPRIETARY NAME AND 510(k) NUMBER

BIO-RAD QCS Assayed Control
510(k) Number: k000875

5. INTENDED USE

The Randox Aldolase Control Level 2 and Aldolase Control Level 3 are intended for *in vitro* diagnostic use as assayed quality control materials for the quantitative determination of aldolase on the clinical chemistry analyzers indicated in the package insert. This device is for prescription use only.

6. DEVICE DISCRIPTION

Randox Aldolase Control is manufactured at two levels, Level 2 and Level 3. Each control is prepared from human serum with added constituents of human origin, chemicals, stabilizers and preservatives. They are supplied in lyophilized form in 3x1 mL vials and require reconstitution with 1 mL of distilled water.

7. PREDICATE DEVICE COMPARISON TABLE

Comparison of Randox Aldolase Controls Level 2 and 3 with the Predicate Device

Similarities and Differences		
CHARACTERISTICS	**RANDOX ALDOLASE CONTROLS LEVEL 2 AND 3** *(New Device)*	**BIO-RAD** **QCS Assayed Control (k000875)** *(Predicate Device)*
INTENDED USE	The Randox Aldolase Control Level 2 and Aldolase Control Level 3 are intended for *in vitro* diagnostic use as assayed quality control materials for the quantitative determination of aldolase on the clinical chemistry analyzers indicated in the package insert. This device is for prescription use only.	An assayed quality control serum to monitor the precision of laboratory testing procedures for the numerous analytes listed in the package insert
FORMAT	Lyophilised	Lyophilised
MATRIX	Human Serum	Human Serum
STORAGE (Unopened)	2 to 8 °C Until expiration date	2 to 8°C Until expiration date
OPEN VIAL CLAIM	5 days when stored at 2 to 8 °C after reconstitution	Analyze Aldolase as soon as possible after reconstitution due to rapid decrease in activity with time
SIZE	1ml	5ml
Shelf life	24 months when stored at 2 to 8°C	48 months when stored at 2 to 8°C

8. SUMMARY OF STABILTY STUDIES

Opened: Store refrigerated (+2°C to +8°C). Reconstituted Aldolase is stable for 5 days at +2°C to +8°C

if kept capped in the original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should not be returned to the original vial.

The reconstituted stability of Aldolase was determined by reconstituting vials of Aldolase Controls and storing them at +2°C to +8°C for 5 days.

Unopened: Store refrigerated (+2°C to +8°C). Stable to the expiration date printed on individual vials. The Aldolase Controls have been assigned a shelf life of 24 months. This has been tested using real time studies, three batches of the Aldolase controls have been stored at +2°C to +8°C for a period of at least 24 months and all three batches have passed real time stability testing.

9. SUMMARY OF VALUE ASSIGNMENT

An assigned value is calculated for each new batch of Randox Aldolase Controls by nest testing. Nest testing involves assessment of the new lot of controls against a master lot of controls or calibrators. Ten replicates of the test controls are assessed on two or more systems and the mean and CV calculated. The recovery of the master lot is also measured. In the instructions for use there are system specific values quoted and a consensus mean. A range is also provided by taking +/- 25% of the assigned system specific values and the consensus mean. The acceptance criteria states the precision measured by the CV should be less than or equal to 3%, unless the concentration of aldolase in <10% then precision should be less than or equal to 6%.

RX Daytona

Aldolase Control Level	Target Value (IU/L)	N	System Specific Value (IU/L)	CV%
2	7.67	10	7.53	4.3
3	18.3	10	18.1	2.9

Beckman Coulter AU640

Aldolase Control Level	Target Value (IU/L)	N	System Specific Value (IU/L)	CV%
2	7.67	10	7.79	3.1
3	18.3	10	18.4	1.8

10. TRACEABILITY

Analyte	**Supplier**	**Product Number**	**Origin**	**Source**
Aldolase	Sigma	A2714	Rabbit Muscle	Commercial Source, added volumetrically

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Randox Laboratories
C/O Pauline Armstrong
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United Kingdom (UK)

July 18, 2013

Re: K131776
Trade/Device Name: Aldolase Control Level 2 and Aldolase Control Level 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Single (Specified) Analyte Controls
Regulatory Class: I, reserved
Product Code: JJX
Dated: June 10, 2013
Received: June 17, 2013

Dear Ms. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Yung W. Chan -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131776

Device Name: Aldolase Control Level 2 and Aldolase Control Level 3

Indication for Use:

The Randox Aldolase Controls Level 2 and Aldolase Control Level 3 are intended for *in vitro* diagnostic use as assayed quality control materials for the quantitative determination of Aldolase on the clinical chemistry analysers indicated in the package insert. This device is for prescription use only.

This *in vitro* diagnostic device is intended for prescription use only.

Prescription Use ✓ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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